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07/565,673	08/10/1990	JOHANNES C. VAN DER LAAN		8222

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EXAMINER	
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BEFORE THE BOARD OF PATENT APPEALS

AND INTERFERENCES

Paper No. 70

Application Number: 07/565,673

Filing Date: August 10, 1990

Appellant(s): Van der Laan et al.

Lynn Marcus-Wyner

For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed April 23, 2002.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

Appellant's brief includes a statement that claims 41-55 do not stand or fall together and provides

reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

No prior art is relied upon by the examiner in the rejection of the claims under appeal.

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 41-47, 54, and 55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite. This rejection is set forth in prior Office Action, Paper No. 64.

Claims 41-55 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in a way as to reasonably convey to one skilled in the art that the inventor had possession of the claimed invention. This rejection is set forth in prior Office Action, Paper No. 64.

Claims 41-55 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to make and/or use

the invention. This rejection is set forth in prior Office Action, Paper No. 64.

(11) Response to Argument

(a) Claims 41-47 are indefinite under 35 U.S.C. 112, second paragraph, since the specific amino acid residues in the claimed "mutant high alkaline protease" are not specifically defined.

Appellants argue that the phrase "mutant high alkaline protease" is not necessarily indefinite although the specification does not explicitly state the exact amino acid residues that must be mutated in order to make or produce a "mutant high alkaline protease" that has physiochemical properties which differ from the wild-type high alkaline protease. Appellants argue that the specification states that a high alkaline protease is a protease obtained from an alkalophilic *Bacillus* strain. Appellants argue that one of skill in the art would have an understanding of the phrase "mutant high alkaline protease" based on the specification and prior art.

One of skill in the art cannot determine the metes and bounds of the claimed invention since it is unclear what specific amino acid residues are to be mutated in the "mutant high alkaline protease" so as to make or produce a mutant that has different properties compared to the wild-type high alkaline protease. It is unclear when a alkaline protease is or is not a high alkaline protease by obtaining the alkaline protease from any alkalophilic *Bacillus* strain. While the specification provides a general description of how to obtain a mutant protease by genetically manipulating the DNA sequence encoding the wild-type protease, the specific nucleotides which must be mutated in order to make a DNA sequence that encodes a mutant protease with different properties have not been defined in the specification. Thus, the metes and bounds of the claimed invention cannot be determined in light of the specification or prior art.

(b) The phrases "*Bacillus* novo species PB92 and its derivatives" and "*Bacillus* novo species PB92 or derivative thereof" render claims 54 and 55 indefinite.

Appellants argue that absence of a specific definition or a list of *Bacillus* novo species PB92 derivatives in the specification does not render the claims indefinite. Appellants argue that term "derivative" has a common definition and that in the specific case the claimed derivative is derived from *Bacillus* novo species PB92.

One of skill in the art cannot determine the metes and bounds of the claimed invention because it is unclear whether the claimed *Bacillus* novo species PB92 derivatives have the same properties or characteristics of the parent *Bacillus* novo species PB92 or has properties or characteristics that completely differ from the parent *Bacillus* novo species PB92. The claims do not explicitly state that the claimed derivatives do or do not have the properties or characteristics of the parent *Bacillus* novo species PB92. Thus, the metes and bounds of the claimed invention cannot be determined in light of the specification or prior art.

(c) The subject matter in claims 41-55 were not described in the specification in a way as to reasonably convey to one skilled in the art that the inventors had possession of the claimed invention.

Appellants state that the invention encompasses a broad method for the production of mutant proteases in modified *Baciilus* host cells lacking or having a reduced capacity to produce a native protease. Appellants argue that while the examples in the specification describe a specific *Bacillus* novo species PB92, Appellants assert that the specification supports and provides a written description of the broad method contained in the claims. Appellants argue that it unnecessary to describe the amino acid sequences

of many wild-type proteases or mutant proteases.

The claims encompass a gene encoding all possible "mutant high alkaline" proteases and all possible "wild-type high alkaline" proteases. The specification, however, provides only one specific species of the claimed genus of mutant alkaline proteases: a gene encoding a mutant alkaline protease comprising a nucleotide sequence consisting of the gene encoding the wild-type alkaline protease of *Bacillus* novo species PB92 having the codon for M216 replaced with a codon coding for Q, the codon for S160 replaced with a codon coding for D, or the codon of N212 replaced with a codon coding for D. Furthermore, the specification only teaches the wild-type alkaline protease of *Bacillus* novo species PB92 as the single representative species of the claimed "wild-type high alkaline" proteases. The specification only teaches the wild-type alkaline protease of *Bacillus* novo species PB92 as the single representative species of the claimed "wild-type high alkaline" proteases. The specification fails to describe additional representative species of these "mutant high alkaline" proteases or "wild-type high alkaline" proteases. The inventors have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize the inventors were in possession of the claimed invention.

(d) The specification does not provide a written description to support the subject matter of claims 54 and 55.

Appellants state that the claims are directed to a method for producing mutant high alkaline proteases from derivatives of *Bacillus* novo species PB92 and that the examples disclose a specific species of the derivative as *Bacillus* strain PBT110. Appellants argue that it is not necessary to provide a written

description for all of the claimed *Bacillus* novo species PB92 derivatives for use in the claimed broad method of claims 54 and 55.

The claims encompass all possible "mutant high alkaline" proteases, all possible "derivatives" of Bacillus novo species PB92, and all host Bacillus host cells incapable of producing a "wild-type high alkaline" proteases. The specification provides a written description of the wild-type alkaline protease of *Bacillus* novo species PB92. The specification provides a description of a mutant alkaline protease of *Bacillus* novo species PB92 having the codon for M216 replaced with a codon coding for Q, the codon for S160 replaced with a codon coding for D, or the codon of N212 replaced with a codon coding for D.

The specification does not provides a written description of any other "derivative" of *Bacillus* novo species PB92, any other "wild-type high alkaline" protease, or any other "mutant high alkaline" protease. Inventors have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize inventors were in possession of the claimed invention.

(e) The specification does not enable the broad scope of the invention of claims 41-55.

Appellants argue that the claims are not to be limited to the examples or preferred embodiments described in the specification. Appellants argue that specification provides guidance for cloning and transformation techniques and production of non-reverting alkaophilic *Bacillus* strain hosts. Appellants argue that requiring disclosure of all possible embodiments of the invention is not an appropriate test for enablement.

The standard for meeting the enablement requirement is whether one of skill in the art can make the invention without undue experimentation. The amount of experimentation to practice the claimed

invention is enormous and undue. The experimentation involves screening for an organism containing a wild-type alkaline protease, selecting and isolating a wild-type alkaline protease from the selected biological source, obtaining the amino acid sequence of the isolated wild-type alkaline protease, obtaining the gene encoding the isolated wild-type alkaline protease from libraries constructed from the selected biological source, recombinantly expressing the wild-type protease using the gene encoding the wild-type protease to verify that the gene encodes the protease, and deleting the gene encoding the wild-type protease in a host cell. Furthermore, such experimentation entails selecting a wild-type alkaline protease to mutate, selecting a mutation to perform on the amino acid sequence of the wild-type alkaline protease such as substitution, addition, deletion, or combinations thereof of amino acid residues, obtaining the gene encoding the selected wild-type alkaline protease, mutate the gene encoding the wild-type alkaline protease, express the mutant alkaline protease, and screening for mutants that still have alkaline protease activity.

In view of the quantity of experimentation necessary, the limited working examples, the unpredictability of the art, the lack of sufficient guidance in the specification and the breadth of the claims, it would take an undue amount of experimentation for one skilled in the art to practice the claimed invention.

It is respectfully submitted that the rejection of all claims in this application is correct and proper for the reasons noted in the rejection above and should be affirmed.

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[Confer]

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Respectfully submitted,
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October 21, 2002

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